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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,178	01/11/2002	Noriyuki Kasahara	06666-022002	7589

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EXAMINER	
NGUYEN, DAVE TRONG	
ART UNIT	PAPER NUMBER
1632	6

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,178	KASAHARA ET AL.	
	Examiner	Art Unit	
	Dave T Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *25 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-46,49-51,56,58-61 and 63-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *41-46, 49-51, 56, 58-61, 63-82* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 49, 50, 70-71, 80, drawn to a method of treatment of a cell proliferative disorder, wherein a recombinant replication competent murine leukemia virus (MLV) or Moloney murine leukemia virus (MoMLV) is employed, classifiable in class 424, subclass 92.

II. Claim 49, drawn to a method of treatment of a cell proliferative disorder, wherein a recombinant replication competent Gibbon ape leukemia virus (GALV) is employed, classifiable in class 424, subclass 92.

III. Claim 49, drawn to a method of treatment of a cell proliferative disorder, wherein a recombinant replication competent Human Foamy Virus (HFV) is employed, classifiable in class 424, subclass 92

For Inventions I-III, claims 41-43, 51-61, 66-69, 72-79, 81, 82 are identified as the linking claims. Note that claims 61-61 appear to contain typographical errors. The claims are dependent from the method of claim 41, and yet are claims as the retrovirus of claim 41.

Should Group I, II, or III be elected, a further group restriction is required as follows:

IV. Claims 44, 45, drawn to an *in vivo* gene therapy method of treatment of a cell proliferative disorder, classifiable in class 424, subclass 93.2.

V. Claims 46, drawn to an *ex vivo* gene therapy method of treatment of a cell proliferative disorder, classifiable in class 424, subclass 93.21.

For Inventions VI and VIII, claims 41-43, 47-61 are identified as the linking claims.

Note that the restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), as listed above. Upon the allowance of the linking claims, the restriction requirement as to the liked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such (claim(s) depending from or including all the limitations of the allowable lining claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler,* 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III Inventions I-III are distinct because each of the inventions is directed to a particular retrovirus wherein the genome is structurally distinct and is expect to generate distinct functional effect particularly in an *in vivo* environment. For example, HFV is not the same as MoLV structurally and functionally. In addition, *in vivo* gene therapy method and *ex vivo* gene therapy method are drawn to materially distinct steps, wherein the step of administering genetically and retrovirally engineered cells for treatment is clearly distinct from the step of an *in vivo* administering a solution containing replication competent retroviral particles. Such distinct and essential steps of administration for each of the respective method would be expected to generate distinct consideration and examination of prior art.

Should any of Inventions I-V be elected, a following species restriction is required:

A specifically named cell proliferative disorder as listed in claim 56, for example. Each of the listed disorder is drawn to a particular type of tumor and/or tissue having a tumor wherein a search of prior art and subsequent examination of each of the listed ones is not necessarily overlapped with each other.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of a specific named disprder as recited in the to be elected claimed invention even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, it would be unduly burdensome for the examiner to search and examine for patentability of all of the claimed inventions, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051.**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER